K102338

SECTION 5. 510(k) SUMMARY

JAN 12 2011

5.1 Date: August 13, 2010

5.2 Submitter:

Name: Akers Biosciences, Inc

Address: 201 Grove Road

Thorofare, New Jersey, 08086

Telephone: 856-848-8698

Contact: Barbara A. Bagby

5.3 Device:

Trade or Proprietary Name: BreathScan®PRO

Common or usual Name: Breath-alcohol test

Classification Name: Devices, Breath Trapping, Alcohol

Product Code: DJZ

Regulation Number: 862.3050

5.4 Predicate Device:

BreathScan®PRO is equivalent to:

Breath Alcohol ☑® *.02* Detection System manufactured by ABI (K062971)

5.5 Indications for Use

The BreathScan®PRO is an *in vitro* medical device that quantitatively detects the presence of alcohol in the human breath. The system is used only as a screening device and is an indication of the presence of alcohol in the blood of the test subject.

5.6 Description of the device

The BreathScan®PRO is quantitative screening test for alcohol in the human breath and provides a digital readout. The BreathScan®PRO consists of a self-contained electronic analyzer to quantitatively detect the presence of alcohol in the human breath. The detection level range is from 0.00% to 0.15%. Breath Alcohol concentrations higher than 0.15% will be displayed as BAC >0.15%. The electronic Analyzer is factory pre-calibrated and is ready to use when a Detector is fully inserted into the sample port. It is a re-usable device designed for use specifically with BreathScan®PRO detectors.

The detectors are disposable screening devices designed for one time use. The BreathScan®PRO Electronic Analyzer enables the user to read or interpret their BreathScan®PRO Detectors charged by human breath. The system provides an indication of the possible presence of alcohol in the blood of the test subject.

The detectors contains chemicals that change color in the presence of alcohol vapors) utilizing the patented technology. The Detector consists of two parts. One part is a glass capsule containing light yellow crystals that change color when exposed to alcohol vapors. The other part is a plugged, plastic tube with an opening to blow into while running the test.

When the subject exhales into the tube, the fresh crystals interact with breath vapor and change color from yellow to blue green if alcohol is present. Note: The resulting color change is dependent upon the level of alcohol detected.

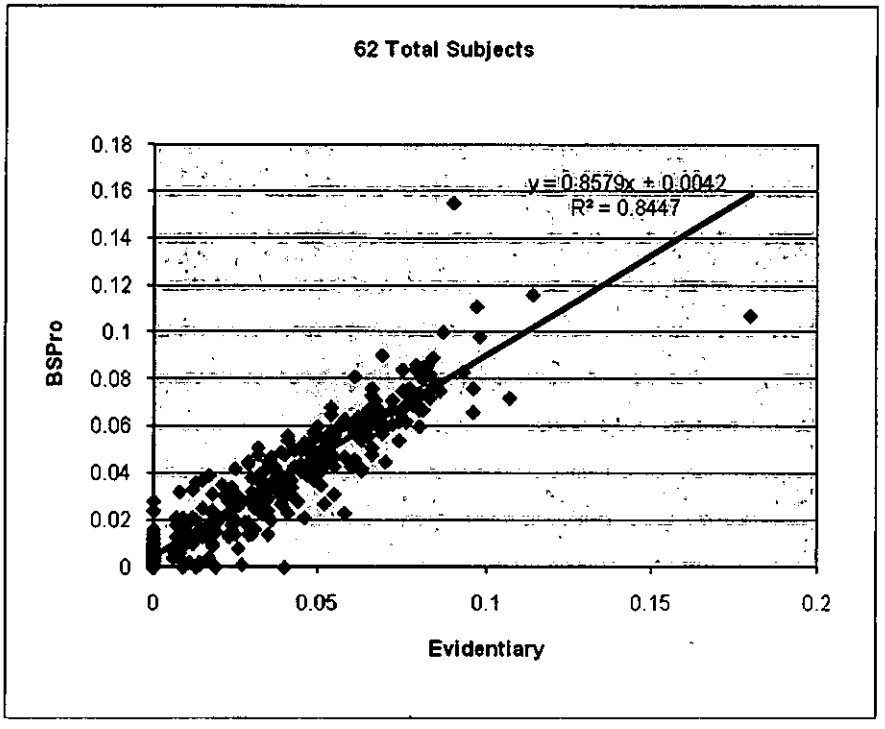
The blow bags are re-usable and serve as a method to assure that the subject has blown through the Detector with adequate air. With the BreathScan®PRO, this is required (DOT/NHTSA compliance). ABI provides these in the starter kit and as an option for future orders.

5.7 Safety and Effectiveness

The bench test and user testing data indicated that the BreathScan®PRO is safe and effective as an evidentiary breath test, the ALCO SENSOR IV manufactured by Intoximeters, Inc. which is a DOT/NHTSA approved device (Conforming Products List of Evidentiary Breath Measurement Devices – FR/Vol.69, No.134/July 2004/Notices/42237).

User studies were performed to establish that the user could read and understand the directions provided and properly use the devices (Table 1).

Table 1
Comparison to Evidentiary Breath Test (Alco-Sensor IV)



Standard Error = 0.01

Additionally, the BreathScan®PRO was evaluated and found to meet the guidelines provided in the DOT/NHTSA Model Specifications for Alcohol Screening Devices –(Federal Register/Vol. 73, No. 62, March 31, 2008/Notices/16956).

5.8 Substantial Equivalence

The similarities and differences between the BreathScan®PRO and the Breath Alcohol ✓® *.02* Detection System is summarized in Table 2.

Table 2

Similarities and Difference Between the BreathScan®PRO *and the* Breath Alcohol ☑® *.02* Detection System

SIMILARITIES		
Parameter	**Device**	**Predicate Device**
	BreathScan®PRO	Breath Alcohol ☑® *.02* Detection System K062971
Indications for Use	Detect the presence of alcohol in human breath.	Detect the presence of alcohol in human breath.
Target Populations	Over the Counter	Over the Counter
Display	Digital Read out	Red, Green LEDs
Calibration/Accuracy Checks	None required	None required
Result	Quantitative	Qualitative
Construction	Plastic case with internal circuit board	Plastic case with internal circuit board

DIFFERENCES		
Parameter	**Device**	**Predicate Devices**
Test Sample	BreathScan®PRO	Breath Alcohol ☑® .02 Detector charged with human breath
Mouthpiece	None required	None required
Anatomical Site	Mouth	Mouth
Instrument System	Reflectance Measurement	Reflectance Measurement
Measurement Range	Defined limits, 0.00% to 0.15% (higher levels displayed as >0.15%) BAC	Defined limits, <.02% = Green flashing LED (negative) and ≥.02% Red flashing LED (positive)
Warm Up Time	None	None
Dimensions	5 ½ by 4 1/8 inches	2 by 3 3/8 inches
Weight	250 grams	75 grams
Battery Life	2000 measurements	1000 measurements
Power Source	1Lithium 9 volt (built in)	2- CR2032 batteries (built in)

5.9 Conclusions

After analyzing bench test and user testing data, it is the conclusion of Akers Biosciences, Inc. that the BreathScan®PRO is as safe and effective as the predicate and comparative devices. Users studies showed that the over the counter purchaser of this device could read and understand the instructions, could properly use the device and obtain results that were comparable to those provided by a predicate device administered by a trained technician.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Akers Biosciences, Inc.
c/o Barbara Bagby
201 Grove RD.
Thorofare, NJ 08086

Re: k102338
Trade/Device Name: BreathScan Pro

Regulation Number: 21 CFR 862.3050
Regulation Name: Breath-alcohol test system
Regulatory Class: Class I, reserved
Product Code: DJZ
Dated: December 23, 2010
Received: December 27, 2010

JAN 12 2011

Dear Ms. Bagby:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

JAN 12 2011

510(k) Number (if known): _____K102338_____

Device Name: ____ BreathScan®PRO_____

Indications for Use:

The BreathScan®PRO is an in vitro medical device that quantitatively the presence of alcohol in the human breath. The device is used only as a screening device and is an indication of the possible presence of alcohol in the blood of the test subject.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ✓ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K102338